

HELLSTROM et al
Appl. No. 10/578,848
December 15, 2008

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The claims have been amended to define the invention with additional clarity.

Claims 1-3 and 7-12 stand rejected under 35 USC 102(b) as allegedly being by Neurath et al (EP1564902A). These same claims also stand rejected under 35 USC 102(b) as allegedly being by Neurath et al (EP448126A) and, it is believed, Neurath et al (USP 4,847,080) (the Examiner indicates that it is claims 13-19 that are rejected over of USP 4,847,080 but, since claims 13-19 have been cancelled, it is believed that claims 1-3 and 7-12 were intended – the Examiner is, however, requested to clarify the record in the next Office Action). Withdrawal of these rejections is submitted to be in order for the reasons that follow.

Applicants submit that, in rejecting the claims as anticipated, the Examiner has not given weight to the preamble or the phrase “*the presence of said antibodies in said sample being indicative that said individual will respond to said treatment*” in the absence of any active method step for the “predicting” aspect.

Claim 1 has been amended to recite an active step of predicting from the presence or absence of anti-preS1 (94-117) antibodies whether or not the individual will respond to IFN α treatment. This active predicting step is a limiting feature of claim 1 which should be given full patentable weight.

Neurath et al (EP1564902A), Neurath et al (EP448126A) and Neurath et al (US4,847,080) do not contain any teaching whatsoever regarding the prognostic or predictive value of anti-preS1 94-117 antibodies for the outcome of hepatitis B, nor do any of these documents disclose a correlation between the presence of preS1 (94-117) antibodies in an

HELLSTROM et al
Appl. No. 10/578,848
December 15, 2008

individual who has been diagnosed with an HBV infection and the responsiveness of the individual to IFN α treatment.

In the absence of such teachings, neither Neurath et al (EP1564902A), Neurath et al (EP448126A) nor Neurath et al (US4,847,080) disclose the active method step of predicting whether or not the individual will respond to IFN α treatment. In the absence of any disclosure of a step of predicting the responsiveness of the individual to IFN α therapy from the presence or absence of preS1 (94-117) antibodies, instant claims 1 to 3 and 7 to 12 are novel over any one of Neurath et al (EP1564902A), Neurath et al (EP448126A) and Neurath et al (US4,847,080). Reconsideration of the rejections raised under 35 USC 102(b) is, therefore, requested.

Claims 4-6, 20 and 22 stand rejected under 35 USC 103(a) as allegedly being obvious over Neurath et al (EP1564902A), Neurath et al (EP448126A) or Neurath et al (US4,847,080), in view of Zavaglia et al. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

Neurath et al (EP1564902A), Neurath et al (EP448126A) and Neurath et al (US4,847,080) all teach peptides for use as HBV immunogens and vaccines, which comprise at least six consecutive amino acids encoded by the pre-S region of the env gene of HBV. Zavaglia et al teaches that interferon- α inhibits HBV replication in a minority of patients with chronic hepatitis B.

The combination of Neurath et al (EP1564902A), Neurath et al (EP448126A), Neurath et al (US4,847,080) and Zavaglia et al would have failed to teach or suggest any correlation between the presence of preS1 (94-117) antibodies and the responsiveness of the individual to IFN α therapy. In the absence of disclosure of this correlation, one of ordinary skill in the art would have been unable to predict the responsiveness of the individual to IFN α therapy from the

HELLSTROM et al
Appl. No. 10/578,848
December 15, 2008

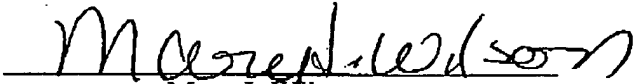
presence of preS1 (94-117) antibodies. The step of predicting responsiveness to IFN α therapy is a limiting feature of the claimed methods. In the absence of any disclosure of such a step, the combination of Neurath et al (EP1564902A), Neurath et al (EP448126A), Neurath et al (US4, 847,080) and Zavaglia et al would not have suggested the claimed invention and reconsideration is requested..

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:


Mary J. Wilson
Reg. No. 32,955

MJW:tat
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100